September 10, 2018

Trevena to Present Oliceridine, a Next Generation IV Opioid for the Management of Moderate to Severe Acute Pain, at FDA Advisory Committee Meeting on October 11, 2018

CHESTERBROOK, Pa., Sept. 10, 2018 (GLOBE NEWSWIRE) -- Trevena, Inc. (NASDAQ: TRVN), today announced that the U.S. Food and Drug Administration (FDA) has scheduled a meeting of the Anesthetic and Analgesic Drug Products Advisory Committee on October 11, 2018 in Silver Spring, MD, to discuss the safety and efficacy of oliceridine injection for the management of moderate to severe acute pain.

The Company‘s New Drug Application (NDA) submission for oliceridine was accepted for review by the FDA on January 2, 2018. The Prescription Drug User Fee Act (PDUFA) target date for completion of review by FDA of November 2, 2018 remains unchanged.

“We look forward to the Advisory Committee meeting on October 11 and the opportunity to present our perspectives on the oliceridine clinical data and its potential role in treating moderate to severe acute pain,” said Maxine Gowen, President and Chief Executive Officer. “We remain committed to working closely with the FDA towards achieving the goal of ensuring hospital patients who require an IV opioid to manage their moderate to severe acute pain have access to effective and safe treatment options.”

Members of the Anesthetic and Analgesic Drug Products Advisory Committee will review and evaluate available data regarding safety and effectiveness and make appropriate recommendations. All final decisions will be made by the FDA.

About Oliceridine Injection

Oliceridine injection is an investigational next generation IV analgesic for the management of moderate to severe acute pain in the hospital and similar settings and has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration (FDA). Oliceridine injection was specifically designed to improve conventional opioid pharmacology to deliver the pain-reducing potential of an opioid but with fewer opioid-related adverse effects. Oliceridine is an investigational product and has not been approved by the FDA or any other regulatory agency. If approved, the Company expects oliceridine to be a Schedule II controlled substance.

About Trevena

Trevena, Inc. is a biopharmaceutical company developing innovative therapies based on breakthrough science to benefit patients and healthcare providers confronting serious

medical conditions. The Company has discovered four novel and differentiated drug candidates, including oliceridine injection, for the management of moderate-to-severe acute pain, TRV250 for the treatment of acute migraine, and TRV734 for pain. The Company maintains an early stage portfolio of drug discovery programs.

Cautionary note on forward looking statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about the Company's strategy, future operations, clinical development of its therapeutic candidates, plans for potential future product candidates and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the status, timing, costs, results and interpretation of the Company's clinical trials or any future trials; the uncertainties inherent in conducting clinical trials; interpretations of regulatory interactions and expectations for regulatory submissions and approvals, including whether the; availability of funding sufficient for the Company's foreseeable and unforeseeable operating expenses and capital expenditure requirements; uncertainties related to the Company's intellectual property; other matters that could affect the availability or commercial potential of the Company's therapeutic candidates; and other factors discussed in the Risk Factors set forth in the Company's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission (SEC) and in other filings the Company makes with the SEC from time to time. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments may cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so, except as may be required by law.

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